



STATE BOARD OF EQUALIZATION

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State Controller

CYNTHIA BRIDGES
Executive Director

June 6, 2014

Dear Interested Party:

Enclosed is the Initial Discussion Paper on proposed Regulation 1591, *Medicines and Medical Devices*. Before the issue is presented at the Board's November 18, 2014 Business Taxes Committee meeting, staff would like to invite you to discuss the issue and present any additional suggestions or comments. Accordingly, an interested parties meeting is scheduled as follows:

June 16, 2014
Room 122 at 10:00 a.m.
450 N Street, Sacramento, CA

If you would like to participate by teleconference, call 1-888-636-3807 and enter access code 499201. You are also welcome to submit your comments to me at the address or fax number in this letterhead or via email at Susanne.Buehler@boe.ca.gov by June 27, 2014. Copies of the materials you submit may be provided to other interested parties, therefore, ensure your comments do not contain confidential information. Please feel free to publish this information on your website or distribute it to others that may be interested in attending the meeting or presenting their comments.

If you are interested in other Business Taxes Committee topics refer to our webpage (<http://www.boe.ca.gov/meetings/btcommittee.htm>) for copies of discussion or issue papers, minutes, a procedures manual, and calendars arranged according to subject matter and by month.

Thank you for your consideration. We look forward to your comments and suggestions. Should you have any questions, please feel free to contact our Business Taxes Committee staff member Mr. Michael Patno at Michael.Patno@boe.ca.gov or 1-916-327-2045, who will be leading the meeting.

Sincerely,

Susanne Buehler, Chief
Tax Policy Division
Sales and Use Tax Department

SB: map
Enclosures

cc: (all with enclosures)

Honorable Jerome E. Horton, Chairman, Fourth District
Honorable Michelle Steel, Vice Chair, Third District
Honorable Betty T. Yee, Member, First District (MIC:71)
Senator George Runner (Ret.), Member, Second District (via email)
Honorable John Chiang, State Controller, c/o Ms. Marcy Jo Mandel

(via email)

Mr. David Hunter, Board Member's Office, Fourth District
Ms. Jaclyn Appleby, Board Member's Office, Fourth District
Mr. Neil Shah, Board Member's Office, Third District
Mr. Tim Treichelt, Board Member's Office, Third District
Mr. Alan LoFaso, Board Member's Office, First District
Ms. Mengjun He, Board Member's Office, First District
Ms. Yvette Stowers, Board Member's Office, First District
Mr. Ramon Salazar, Board Member's Office, First District
Mr. Sean Wallentine, Board Member's Office, Second District
Mr. James Kuhl, Board Member's Office, Second District
Mr. Lee Williams, Board Member's Office, Second District
Ms. Lynne Kinst, Board Member's Office, Second District
Ms. Tanya Vandrick, Board Member's Office, Second District
Mr. Alan Giorgi, Board Member's Office, Second District
Ms. Natasha Ralston Ratcliff, State Controller's Office
Ms. Cynthia Bridges (MIC:73)
Mr. Randy Ferris (MIC:83)
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Mr. Jeff Vest (MIC:85)
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Mr. David Levine (MIC:85)
Mr. Robert Tucker (MIC:82)
Mr. Bradley Heller (MIC:82)
Mr. Scott Claremon (MIC:82)
Mr. Lawrence Mendel (MIC:82)
Mr. Todd Gilman (MIC:70)
Ms. Laureen Simpson (MIC:70)
Mr. Bill Benson (MIC:67)
Mr. Joe Fitz (MIC:67)
Mr. Wayne Mashihara (MIC:46)
Mr. Kevin Hanks (MIC:49)
Mr. Bradley Miller (MIC:92)
Ms. Kirsten Stark (MIC:50)
Mr. Clifford Oakes (MIC:50)
Mr. Michael Patno (MIC:50)
Mr. Robert Wilke (MIC:50)

INITIAL DISCUSSION PAPER

Proposed Revisions to Regulation 1591, *Medicines and Medical Devices*

Issue

Should Regulation 1591, *Medicines and Medical Devices*, be revised to clarify that the definition of “medicines” includes devices implanted to mark the location of a medical condition?

Background

Revenue and Taxation Code (RTC) section 6369, as interpreted and implemented by Regulation 1591, provides that the sales or use of medicines are not subject to tax if they are sold or otherwise transferred under specified circumstances. In section 6369, subdivision (b), “medicines” are defined as “any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use.” Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicine, including “(2) Articles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof.” However, section 6369, subdivision (c), includes additional specific items that are, notwithstanding subdivision (b), considered to be medicines.

Regulation 1591 has been revised over the years to clarify the definition of “medicines,” but in general it closely resembles the structure of section 6369. Regulation 1591, subdivision (a)(9) defines “medicines” as follows:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

Subdivision (b), in addition to defining and providing examples of preparations and similar substances, includes specific examples of articles, devices and appliances which are included or excluded from the definition of medicines, either generally or for specific uses. Additional exclusions from the definition of medicine are identified in subdivision (c).

In order for the sale of a medicine to be exempt from California Sales and Use tax, the item must first meet the definition of a medicine, and be sold or furnished under one of the conditions described in subdivision (d) of Regulation 1591. Specifically, in relevant part, subdivision (d) requires that the medicine be:

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(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

February 2014 Board Meeting

During the February 2014 Board Meeting, the Members heard a sales and use tax appeal hearing involving breast tissue markers (BTMs). At issue was whether BTMs are medicines and therefore exempt from tax when sold or furnished under the prescribed conditions. The BTMs discussed in the hearing were purchased from out-of-state by a hospital which paid use tax to the Board and then filed claims for refund for the use tax paid.

BTMs are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. A doctor inserts the BTM in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site so that it can be accurately identified by ultrasound, MRI or other imaging methods at a future date. The United States Food and Drug Administration (FDA) allowed the marketing of BTMs and classified them as Class II medical devices. A letter from the FDA to Inrad, Inc., the manufacturer of the BTMs, indicated the manufacturer was allowed to “market the device.” The BTMs were not subject to the FDA’s premarket approval process.

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During the hearing, the taxpayer's representative stated that the BTMs are devices that are fully implanted in a person and are approved for marketing by the FDA to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition, and therefore meet the definition of medicine provided in Regulation 1591, subdivision (a)(9)(A). The taxpayer's representative also stated that the BTMs were not the type of article that is excluded from the definition of medicine by subdivision (c)(2). Conversely, staff stated that a BTM is a "device" which is a type of "article" excluded under subdivision (c). Furthermore, though they are permanently implanted in the human body and aid patients during their medical treatments, BTMs do not assist the functioning of any organ, artery, vein or limb as currently specified by subdivision (b)(2), *Permanently Implanted Articles*. Finally, staff contended that BTMs were not "approved" by the FDA. The Board unanimously voted in favor of the claimant and asked BTC staff to propose revisions clarifying the definition of medicines to include BTMs.

Discussion – Should breast tissue markers be included in the definition of a medicine?

Staff determined that BTMs and similar devices perform much the same function as contrast dyes and opaques used in x-ray and other imaging technology, which are included in the definition of medicines, and therefore BTMs should also be included in the definition of medicines. Since BTMs are permanently implanted in the body, staff determined that the appropriate placement for revised language including them in the definition of medicines is Regulation 1591, subdivision (b)(2), *Permanently Implanted Articles*. The manufacturer's marketing materials appear to indicate the BTMs remain in the human body for an indefinite amount of time and staff therefore considers them to be permanently implanted. The proposed revisions add language to include permanently implanted articles that mark a location of a medical condition as a medicine. Staff has included BTMs as a specific example of a device that performs such a function.

Discussion – Does the definition of medicines contained in subdivision (a)(9)(A) need clarification?

At the February 2014 Board meeting, the Board discussed the definition of medicines as it pertains to medical devices and the complicated nature of FDA classifications of those medical devices. A device, which would generally be excluded under subdivision (c), but is considered a medicine for some uses under subdivision (b) and meets the other elements of subdivision (a)(9)(A), will be considered a medicine for all uses pursuant to subdivision (a)(9)(A). However, if a device does not fall under one of the specific definitions contained in subdivision (b), then it is excluded from the definition of medicines under subdivision (c) without exception, and subdivision (a)(9)(A) does not apply. Staff's proposed revisions to Regulation 1591 will clarify the original intent that the definition of medicines in subdivision (a)(9)(A) for devices and other products does not apply if they are generally excluded from the definition under subdivision (c). However, if a product has multiple uses, it can be defined as a medicine if one of the uses meets a subdivision (b) description.

Most medical devices are considered Class II devices. They generally are subject to Section 510(k) of the Food, Drug and Cosmetic Act, which requires the device manufacturers to notify the FDA of their intent to market a medical device. This is known as premarket notification or 510(k). A 510(k) is a premarket submission made to the FDA to demonstrate that the device to

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be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR § [807.92\(a\)\(3\)](#)) that is not subject to premarket approval. Generally, a new device that contains new materials or differs in design from products already on the market requires premarket approval by the FDA.

It was noted that a device may not require pre-market approval simply because similar devices, which may have required pre-market approval, are already on the market. Additionally, it was noted that although Class II devices are generally subject to pre-market notification, and Class III devices are generally subject to pre-market approval, such is not always the case. As a result, with regard to devices that meet all other elements of subdivision (a)(9)(A), staff's prior position that "approved by the U.S. Food and Drug Administration" only refers to pre-market approval, could exclude devices of the type that the Board intended to include in the definition of medicine when it added the subdivision. Therefore, staff proposes adding an additional sentence to subdivision (a)(9)(A), clarifying that "approved by the United States Food and Drug Administration (FDA)" refers to either pre-market approval or clearance for a pre-market notification.

Staff proposes amending the subdivision (a)(9)(A) as follows:

~~*Except where taxable for all uses as provided in subdivision (c), aAny product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. United States Food and Drug Administration (FDA) to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, unless the item is specifically excluded from the definition of medicine under subdivision (c) for all uses.*~~

For purposes of this subdivision, with respect to medical devices, "approved by the United States Food and Drug Administration" means any device for which a premarket notification was cleared by the FDA or for which an application for premarket approval was approved by the FDA.

Discussion - Non-Substantive Revisions

In addition to the proposed amendments regarding BTMs, staff proposes non-substantive amendments. These revisions include the references of other governmental agencies in order to keep consistency throughout the regulation. Staff also implemented the use of abbreviations for the various codes of the California Code of Regulations which are often referred to in the regulation. Minor grammatical errors were noted on the Office of Administrative Law version of the regulation; they were corrected with the revisions as well.

Summary

Staff proposes amendments to Regulation 1591, *Medicines and Medical Devices*, to clarify that a product, such as BTMs, designed to be implanted in the human body to mark the location of a medical condition is included in the definition of a medicine. In addition, references were updated for consistency with other regulations. Staff welcomes any comments, suggestions, and input from interested parties on this issue. Staff also invites interested parties to participate in

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the June 16, 2014, interested parties meeting. The deadline for interested parties to provide written responses regarding this discussion paper is June 27, 2014.

Prepared by the Tax Policy Division, Sales and Use Tax Department

Current as of 06/04/2014.

§ 1591. Medicines and Medical Devices.

(a) Definitions.

(1) Administer. “Administer” means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) Dispense. “Dispense” means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) Furnish. “Furnish” means to supply by any means, by sale or otherwise.

(4) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in Section 1250 of the Health and Safety Code ([HSC](#)), and also includes “clinic” as defined in [HSC](#) sections 1200 and 1200.1 ~~of the Health and Safety Code~~.

(A) [HSC s](#)~~Section 1250 of the Health and Safety Code~~ provides that “health facility” means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) [HSC s](#)~~Section 1200 of the Health and Safety Code~~ provides that “clinic” means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as ~~an~~^{an} incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) [HSC s](#)~~Section 1200.1 of the Health and Safety Code~~ provides that “clinic” also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in [HSC](#) section 1204.1 ~~of the Health and Safety Code~~, such clinics serve patients under the direction of a clinical psychologist as defined in [HSC](#) section 1316.5 ~~of the Health and Safety Code~~, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants,

government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code ([BPC](#)) to patients in the home as an incident to care provided at the clinic facility.

(5) Pharmacist. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of [BPC sSection 4200](#) ~~of the Business & Professions Code~~, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law."

(6) Pharmacy. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of [BPC sSection 4037](#) ~~of the Business and Professions Code~~.

(7) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) Physicians, Dentists, Optometrists, and Podiatrists. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice

their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to [BPC Section 2065](#) ~~of the Business & Professions Code~~, when acting within the scope of that section.

(9) Medicines. “Medicines” means:

(A) ~~Except where taxable for all uses as provided in subdivision (e),~~ Any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S.-United States Food and Drug Administration (FDA) to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, unless the item is specifically excluded from the definition of medicine under subdivision (c) for all uses, ~~or~~

For purposes of this subdivision, with respect to medical devices, “approved by the United States Food and Drug Administration” means any device for which a premarket notification was cleared by the FDA or for which an application for premarket approval was approved by the FDA.

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) “Medicines.” In addition to the definition set forth in subdivision (a)(9) of this section, the term “medicines” means and includes the following items:

(1) Preparations and Similar Substances. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

“Preparations and similar substances” include, but are not limited to, drugs such as penicillin, and other antibiotics, “dangerous drugs” (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. “Preparations and similar substances”

also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) Permanently Implanted Articles. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. [In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines.](#) An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb [or mark the location of a medical condition](#), and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) Artificial Limbs and Eyes. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code [\(RTC\)](#) section 6369(c)(5). Tax

does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) Orthotic Devices. Orthotic devices and their replacement parts, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under [RTC Revenue and Taxation Code](#) section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. “Custom-made biomechanical foot orthosis” means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of Paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

“Custom-made biomechanical foot orthosis” do not include:

- (A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;
- (B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) **Prosthetic Devices.** Prosthetic devices and their replacement parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under [RTC Revenue and Taxation Code](#) section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuffs, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as medicines include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) **Drug Infusion Devices.** Programmable drug infusion devices to be worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an

intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under [RTC Revenue and Taxation Code](#) section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) Exclusions from the Definition of “Medicines.”

Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with [BPC sSection 23000](#), ~~of the Business and Professions Code~~).

(d) Application of Tax - In General

Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) Specific Tax Applications.

(1) Prescriptions. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) Licensed Physician, Dentist or Podiatrist. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) Health Facility. Tax does not apply to sales of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) Pharmaceutical Manufacturer or Distributor. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes,

and the elements and ingredients used to produce the “samples” whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the ~~FDA’s United States Food and Drug Administration’s~~ drug development and approval process. “Clinical trial medicines” are substances or preparations approved as “Investigational New Drugs” by the ~~FDA United States Food and Drug Administration~~ intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. “Clinical trial medicines” do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) Antimicrobial Agents Used by Hospital Personnel. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) Vitamins, Minerals, Herbs, and Other Such Supplements. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of ~~RTC Revenue and Taxation Code~~ section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through ~~gh~~ (d)(6).

(7) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of ~~RTC Revenue and Taxation Code~~ section 6369 when the product does not

otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) ~~of Regulation 1591.~~

(8) Diagnostic Substances, Test Kits, and Equipment. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (“in vitro”) in an artificial environment. They are not administered in the living body (“in vivo”). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under ~~RTC Revenue and Taxation Code~~ section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) Insurance Payments

(1) Medical Insurance and Medi-Cal. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) Medicare

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) Employer Medical Contracts. Certain employers have contracted with their employees to provide the latter with medical, surgical and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) Records.

Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to [BPC sSection 4081](#) ~~of the Business and Professions Code~~, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are “deemed to be dispensed on prescription” within the meaning of Section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) “Double Deduction” Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

Authority cited: Section 7051, Revenue and Taxation Code. Reference: Sections 6006 and 6369, Revenue and Taxation Code; and Sections 1200, 1200.1, 1204.1 and 1250, Health and Safety Code.

Note: Text is from the website of the Office of Administrative Law as of 5/14/14. History was removed for ease of review.